

REMARKS

After entry of the instant paper, claims 1-55 will be pending. Claim 22 has been amended to correct a typographical error which inadvertently lists "type V" in duplicate, where the second "type V" should read "type VIII" as supported throughout the instant specification. For example, support may be found in paragraphs 16 and 20 on pages 3-4 and in the instant claims.

Claims 52-55 have been added. Support may be found throughout the instant specification as originally filed, for example, in paragraph 49, page 8: "The vaccines of the invention comprise purified polysaccharides..." and in paragraph 41, page 7, the term purified means "substantially free of intact polysaccharide capsule or fragments of it having a molecular weight above 100,000."

Claims 1-51 are pending in this application and have been subjected to restriction under 35 U.S.C. §§ 121 because, in the Examiner's opinion, as set forth in the Detailed Action, the application contains claims directed to six (6) patentably distinct inventions as follows:

Group 1: Claims 6-11 and 44-46, drawn to a multivalent conjugate molecule comprising a carrier protein covalently conjugated to GBS type Ia, type III, and type V capsular polysaccharides, or at least three GBS capsular polysaccharides selected from the group consisting of types Ia, Ib, II, III, V, and VIII, classified in class 424, subclass 197.1; and

Group 2: Claims 13-16 and 47-51, drawn to a multivalent conjugate molecule comprising a carrier protein covalently conjugated to the B, C and Y *N. meningitidis* capsular polysaccharides; the C, Y and W-135 *N. meningitidis* capsular polysaccharides; or to at least three *N. meningitidis* capsular polysaccharides selected from the group consisting of A, B, C, W and Y, classified in class 424, subclass 197.1;

Group 3: Claims 22-26, drawn to a method of preparing a multivalent conjugate molecule comprising a carrier protein covalently conjugated to GBS type Ia, type III, and type V capsular polysaccharides, or at least three GBS capsular polysaccharides selected from the group consisting of types Ia, Ib, II, III, V and VIII, classified in class 536, subclass 124;

Group 4: Claims 27-31, drawn to a method of preparing a multivalent conjugate molecule comprising a carrier protein covalently conjugated to the B, C and Y *N. meningitidis* capsular polysaccharides, to the C, Y and W-135 *N. meningitidis* capsular polysaccharides, or to at least three *N. meningitidis* capsular polysaccharides selected from the group consisting of A, B, C, W and Y, classified in class 536, subclass 124;

Group 5: Claims 34-36, drawn to a method of preventing or attenuating GBS infection comprising administering to a mammal a multivalent conjugate comprising a carrier protein conjugated to GBS type Ia, type III, and type V capsular polysaccharides, or at least three GBS capsular polysaccharides selected from the group consisting of types Ia, Ib, II, III, V and VIII, classified in class 424, subclass 244.1; and

Group 6: Claims 37-41, drawn to a method of preventing or attenuating *N. meningitidis* infection comprising administering to a mammal a multivalent conjugate comprising a carrier protein conjugated to B, C and Y *N. meningitidis* capsular polysaccharides; the C, Y and W-135 *N. meningitidis* capsular polysaccharides; or to at least three *N. meningitidis* capsular polysaccharides selected from the group consisting of A, B, C, W and Y, classified in class 424, subclass 249.1.

Applicants provisionally elect **Group 1** with traverse, including claims 6-11 and 44-46 for prosecution. Claims 1-5, 12, 15, 42, and 43 are considered as linking claims and the

Examiner has indicated that these claims would be joined with Group 1 if elected. Furthermore, as newly added claims 52 and 55 are dependent from claims 1 and 42, respectively, these claims also should be joined and considered with the claims of elected Group 1.

Applicants respectfully disagree with the restriction requirement imposed by the Examiner and the characterizations made of the claimed invention. Accordingly, this provisional election is made with traverse.

It is the Examiner's position that restriction is appropriate because the groups contain claims that are not coextensive and have divergent subject matter. Applicants respectfully disagree with the Examiner's position.

According to M.P.E.P. §803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (1) The inventions must be independent or distinct as claimed; **and**
- (2) There must be serious burden on the Examiner if restriction is not required.

Applicants respectfully submit that (1) all groups of restricted claims are properly presented in the same application; (2) undue diverse searching would not be required; and (3) all claims should be examined together.

The Examiner has not shown that examination of all the pending claims would require undue searching and/or place a serious burden on the Examiner, which is a requisite showing for proper issuance of a restriction requirement. In fact, applicants submit that a conjugate molecule and a method of using the conjugate molecule would not be unduly burdensome.

Claims directed to conjugates and methods of those using those conjugates may be classified together. Applicants respectfully submit that searching these groups together would

not be a serious burden on the Examiner as required by M.P.E.P. §803 if restriction is not required. Applicants traverse the restriction requirement between Groups 1 and 2, for the reason that they are both classified in the same class (424) and subclass (197.1) and there should not be a serious burden to search these claims together. Applicants respectfully request that the claims of groups 1 and 2 be examined together.

Applicants further traverse the restriction requirement between groups 3 and 4, for the reason that they are both classified in the same class (536) and subclass (124) and there should not be a serious burden to search these claims together. Applicants respectfully request that the claims of groups 3 and 4 be examined together.

Applicants respectfully request that at least the claims of Group 1, as well as claims of Groups 3 and 5 which are directed to a methods for preparing and using a multivalent conjugate molecule, respectively, be examined together. There would not be a serious burden to search a product and a method of preparing and using the product. In fact, there would be overlap. Accordingly, reconsideration of the restriction/election requirement is respectfully requested. For similar reasons, the claims of Group 2, as well as claims of Groups 4 and 6 which are directed to methods for preparing and using a multivalent conjugate molecule, respectively, should be examined together. There would not be a serious burden to search a product and a method of preparing and using the product.

For the above reasons, it is respectfully requested that the Examiner rejoin Groups 1, 3, and 5 and/or Groups 2, 4, and 6 because it is believed that a search of the art would not cause an undue or serious burden on the Examiner. As the Examiner is aware, should the compounds of elected Group 1 be found patentable, then the methods of preparing and using

those compounds in Groups 3 and 5 should be rejoined according to MPEP §806.05(i). The same holds true for Group 2 and Groups 4 and 6. It is believed that the elected claims are in condition for allowance. Early and favorable action by the Examiner is earnestly solicited.

Additionally, the Examiner requires that applicants should elect one of the specific multivalent GBS conjugate species: (a) type Ia, type III, and type V of claims 7 and 45, claim 23, or 35; and (b) a specific multivalent conjugate species in claims 6 and 44, claim 22 or 34. Applicants provisionally elect **multivalent GBS conjugate Species (a) to GBS type Ia, type III, and type V** with traverse. Claims 1-5, 17-21, 32, 33, 42, and 43 are considered generic. As the Examiner is aware, the Court of Customs and Patent Appeals ("CCPA") held in *In re Weber*, 580 F.2d 455, 458-49, 198 U.S.P.Q. 328, 331-32 (C.C.P.A. 1978), that the PTO cannot require an applicant, under the guise of § 121, to divide up the embodiments of a single Markush claim. *See also In re Watkinson*, 900 F.2d 230, 14 U.S.P.Q.2d 1407 (Fed. Cir. 1990), where the Federal Circuit confirmed the principle that the PTO cannot properly reject a single Markush claim under § 121. Also see M.P.E.P. § 803.02.

The Examiner has further required the election of one of the carrier protein species of claims 5, 8, 15, 16, 21, 24, 30, 31, 33, 36, 40, 41, 43, 46, 50, and 51: (a) C alpha; (b) C beta; (c) tetanus toxoid; (d) diphtheria toxoid; (e) CRM197; and (f) porin protein. Claims 1-4, 6-14, 17-20, 22, 23, 25-29, 32, 34, 35, 37-39, 42, 44, 45, and 47-49 are considered to be generic. Applicants traverse this election requirement for the reasons stated above, and provisionally elect **Carrier Protein Species (b) C beta**.

Applicants further traverse the election of species requirement on the grounds that the art and the USPTO have clearly recognized that groups of specific polysaccharides and/or

carrier proteins are often considered together as the mechanism of eliciting a thymus dependent immune response and is applicable to a wide variety of polysaccharides and carrier proteins.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request that the Restriction Requirement be withdrawn and all presented claims be examined on the merits.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **13-4500**, Order No. 2324-6052US1.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. 2324-6052US1.

Respectfully submitted,
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By: _____



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